

misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(b) *Directions for use.* The labeling of the product contains the recommended dosage per time interval (e.g., every 4 hours) or time period (e.g., 4 times a day) broken down by age groups if appropriate, followed by “except under the advice and supervision of a physician.” The words “or as needed” may be used after the recommended dosage per time interval or time period.

(c) *Exemption from the general accidental overdose warning.* The labeling for antiflatulent drug products containing simethicone identified in §332.10 and antacid/antiflatulent combination drug products provided for in §332.15, containing the active ingredients identified in §331.11(a), (b), and (d) through (m) of this chapter are exempt from the requirement in §330.1(g) of this chapter that the labeling bear the general warning statement “In case of accidental overdose, seek professional assistance or contact a poison control center immediately.” The labeling must continue to bear the first part of the general warning in §330.1(g) of this chapter, which states, “Keep this and all drugs out of the reach of children.”

[39 FR 19877, June 4, 1974, as amended at 40 FR 11719, Mar. 13, 1975; 51 FR 16266, May 1, 1986; 51 FR 27763, Aug. 1, 1986; 52 FR 7830, Mar. 13, 1987]

EFFECTIVE DATE NOTE: At 61 FR 8838, Mar. 5, 1996, in §332.30, was amended by revising the section heading; by redesignating paragraphs (a), (b), and (c) as paragraphs (b), (c), and (d), respectively; by adding new paragraph (a); and by revising newly redesignated paragraph (b), effective March 5, 1997. For the convenience of the reader, the revised text is set forth below.

**§ 332.30 Labeling of antiflatulent drug products.**

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an “antiflatulent,” “antigas,” or “antiflatulent (antigas).”

(b) *Indications.* The labeling of the product states, under the heading “Indications,” one or more of the phrases listed in this paragraph (b), as appropriate. Other truthful and nonmisleading statements, describing only

the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in §330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) (Select one of the following: “Alleviates or Relieves”) “the symptoms referred to as gas.”

(2) (Select one of the following: “Alleviates” or “Relieves”) (select one or more of the following: “bloating,” “pressure,” “fullness,” or “stuffed feeling”) “commonly referred to as gas.”

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**§ 332.31 Professional labeling.**

(a) The labeling of the product provided to health professionals (but not to the general public) may contain as additional indications postoperative gas pain or for use in endoscopic examination.

(b) Professional labeling for an antiflatulent-antacid combination may contain information allowed for health professionals for antacids and antiflatulents.

**PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE**

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AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371), unless otherwise noted.

SOURCE: 52 FR 47322, Dec. 11, 1987, unless otherwise noted.

#### Subpart A—[Reserved]

#### Subpart B—First Aid Antibiotic Drug Products

##### § 333.101 Scope.

(a) An over-the-counter first aid antibiotic drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

##### § 333.103 Definitions.

As used in this subpart:

(a) *Antibiotic drug*. In accordance with section 507(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357(a)), “any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).”

(b) *First aid antibiotic*. An antibiotic-containing drug product applied topically to the skin to help prevent infection in minor cuts, scrapes, and burns.

##### § 333.110 First aid antibiotic active ingredients.

The product consists of any of the following active ingredients within the

specified concentration established for each ingredient and in the specified dosage form:

(a) Bacitracin ointment containing, in each gram, 500 units of bacitracin in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 448.510a(b).

(b) Bacitracin zinc ointment containing, in each gram, 500 units of bacitracin zinc in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 448.513f(b).

(c) Chlortetracycline hydrochloride ointment containing, in each gram, 30 milligrams of chlortetracycline hydrochloride in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 446.510(b).

(d) Neomycin sulfate ointment containing, in each gram, 3.5 milligrams of neomycin in a suitable water soluble or oleaginous ointment base: *Provided*, That it meets the tests and methods of assay in § 444.542a(b).

(e) Neomycin sulfate cream containing, in each gram, 3.5 milligrams of neomycin in a suitable cream base: *Provided*, That it meets the tests and methods of assay in § 444.542b(b).

(f) Tetracycline hydrochloride ointment containing, in each gram, 30 milligrams of tetracycline hydrochloride in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 446.581d(b).

[52 FR 47322, Dec. 11, 1987, as amended at 53 FR 18838, May 25, 1988]

##### § 333.120 Permitted combinations of active ingredients.

The following combinations are permitted provided each active ingredient is present within the established concentration and in the specified dosage form, and the product is labeled in accordance with § 333.160.

(a) *Combinations of antibiotic active ingredients*. (1) Bacitracin-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 448.510d(b).

(2) Bacitracin-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B;

*Provided*, That it meets the tests and methods of assay in § 448.510e(b).

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases: *Provided*, That it meets the tests and methods of assay in § 448.510f(b).

(4) Bacitracin zinc-neomycin sulfate ointment containing, in each gram, 500 units of bacitracin and 3.5 milligrams of neomycin in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 448.513b(b).

(5) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, and 8,000 units of polymyxin B; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, and 5,000 units of polymyxin B; or

(iv) 500 units of bacitracin, 3.5 milligrams of neomycin, and 10,000 units of polymyxin B;

*Provided*, That it meets the tests and methods of assay in § 448.513c(b).

(6) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin and 10,000 units of polymyxin B in a suitable ointment base: *Provided*, That it meets the tests and methods assay in § 448.513a(b).

(7) Bacitracin zinc-polymyxin B sulfate topical aerosol containing, in each gram, 120 units of bacitracin and 2,350 units of polymyxin B in a suitable vehicle, packaged in a pressurized container with suitable inert gases: *Provided*, That it meets the tests and methods of assay in § 448.513e(b) of this chapter.

(8) Bacitracin zinc-polymyxin B sulfate topical powder containing, in each gram, 500 units of bacitracin and 10,000

units of polymyxin B in a suitable base: *Provided*, That it meets the tests and methods of assay in § 448.513d(b).

(9) Neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, 3.5 milligrams of neomycin and 5,000 units of polymyxin B in a suitable water miscible base: *Provided*, That it meets the tests and methods of assay in § 444.542e(b).

(10) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin and 10,000 units of polymyxin B in a suitable vehicle: *Provided*, That it meets the tests, methods of assay, and potency in § 444.5421(b).

(11) Oxytetracycline hydrochloride-polymyxin B sulfate ointment containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B in a suitable ointment base: *Provided*, That it meets the tests and methods assay in § 446.567b(b).

(12) Oxytetracycline hydrochloride-polymyxin B sulfate topical powder containing, in each gram, 30 milligrams of oxytetracycline and 10,000 units of polymyxin B with a suitable filler: *Provided*, That it meets the tests and methods assay in § 446.567c(b).

(b) *Combinations of first aid antibiotic active ingredients and local anesthetic active ingredients.*

(1) Bacitracin ointment containing, in each gram, 500 units of bacitracin and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 448.510a(b).

(2) Bacitracin-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 500 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient.

*Provided*, That it meets the tests and methods of assay in § 448.510e(b).

(3) Bacitracin-polymyxin B sulfate topical aerosol containing, in each gram, 500 units of bacitracin and 5,000 units of polymyxin B and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle, packaged in a pressurized container with suitable inert gases: *Provided*, That it meets the tests and methods of assay in § 448.510f(b) of this chapter.

(4) Bacitracin zinc-neomycin sulfate-polymyxin B sulfate ointment containing, in each gram, in a suitable ointment base the following:

(i) 400 units of bacitracin, 3 milligrams of neomycin, 8,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(ii) 400 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(iii) 500 units of bacitracin, 3.5 milligrams of neomycin, 5,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient; or

(iv) 500 units of bacitracin, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient;

*Provided*, That it meets the tests and methods of assay in § 448.513c(b) of this chapter.

(5) Bacitracin zinc-polymyxin B sulfate ointment containing, in each gram, 500 units of bacitracin, 10,000 units of polymyxin B, and any single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable ointment base: *Provided*, That it meets the tests and methods of assay in § 448.513a(b) of this chapter.

(6) Neomycin sulfate-polymyxin B sulfate cream containing, in each gram, 3.5 milligrams of neomycin, 10,000 units of polymyxin B, and any

single generally recognized as safe and effective amine or "caine"-type local anesthetic active ingredient in a suitable vehicle: *Provided*, That it meets the tests and methods of assay in § 444.542l(b) of this chapter.

[52 FR 47322, Dec. 11, 1987; 52 FR 48792, Dec. 24, 1987, as amended at 53 FR 18838, May 25, 1988; 55 FR 9722, Mar. 15, 1990; 55 FR 40381, Oct. 3, 1990; 55 FR 50172, Dec. 5, 1990]

### § 333.150 Labeling of first aid antibiotic drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as a "first aid antibiotic."

(b) *Indications*. The labeling of the product states, under the heading "Indications," the following: "First aid to help" [select one of the following: "prevent," ("decrease" ("the risk of" or "the chance of")), ("reduce" ("the risk of" or "the chance of")), "guard against," or "protect against"] [select one of the following: "infection," "bacterial contamination," or "skin infection"] "in minor cuts, scrapes, and burns." Other truthful and nonmisleading statements describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings*. The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only. Do not use in the eyes or apply over large areas of the body. In case of deep or puncture wounds, animal bites, or serious burns, consult a doctor."

(2) "Stop use and consult a doctor if the condition persists or gets worse. Do not use longer than 1 week unless directed by doctor."

(d) *Directions*. The labeling of the product contains the following statements under the heading "Directions": (1) *For ointment and cream products*. "Clean the affected area. Apply a small

amount of this product (an amount equal to the surface area of the tip of a finger) on the area 1 to 3 times daily. May be covered with a sterile bandage.”

(2) *For powder products.* “Clean the affected area. Apply a light dusting of the powder on the area 1 to 3 times daily. May be covered with a sterile bandage.”

(3) *For aerosol products.* “Clean the affected area. Spray a small amount of this product on the area 1 to 3 times daily. May be covered with a sterile bandage.”

(e) The word “doctor” may be substituted for the word “physician” in any of the labeling statements in this subpart.

**§ 333.160 Labeling of permitted combinations of active ingredients.**

Statements of identity, indications, warnings, and directions for use, respectively, applicable to each ingredient in the product may be combined to eliminate duplicative words or phrases so that the resulting information is clear and understandable.

(a) *Statement of identity.* For a combination drug product that has an established name, the labeling of the product states the established name of the combination drug product, followed by the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of the applicable OTC drug monographs.

(b) *Indications.* The labeling of the product states, under the heading “Indications,” the indication(s) for each ingredient in the combination, as established in the “Indications” sections of the applicable OTC drug monographs, unless otherwise stated in this paragraph. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in this paragraph (b), may also be used, as provided in § 330.1(c)(2), subject to the provisions of

section 502 of the act relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For permitted combinations identified in § 333.120(a).* The indications in § 333.150 should be used.

(2) *For permitted combinations identified in § 333.120(b).* In addition to the required indication identified in § 333.150, the labeling of the product may state, under the heading “Indications,” the following additional indication: “First aid for the temporary relief of” (select one of the following: “pain,” “discomfort,” “pain or discomfort” or “pain and itching”) “in minor cuts, scrapes, and burns.”

(c) *Warnings.* The labeling of the product states, under the heading “Warnings,” the warning(s) for each ingredient in the combination, as established in the warnings sections of the applicable OTC drug monographs.

(d) *Directions.* The labeling of the product states, under the heading “Directions,” directions that conform to the directions established for each ingredient in the directions sections of the applicable OTC drug monographs. When the time intervals or age limitations for administrations of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

**Subpart C—Topical Antifungal Drug Products**

SOURCE: 58 FR 49898, Sept. 23, 1993, unless otherwise noted.

**§ 333.201 Scope.**

(a) An over-the-counter antifungal drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.

(b) Reference in this subpart to regulatory sections of the Code of Federal

Regulations are to chapter I of title 21 unless otherwise noted.

### § 333.203 Definitions.

As used in this subpart:

(a) *Antifungal*. A drug which inhibits the growth and reproduction of fungal cells and decreases the number of fungi present.

(b) *Athlete's foot*. An infection of the feet caused by certain dermatophytic fungi.

(c) *Dermatophyte*. A fungus that invades and lives upon the skin or in the hair or nails.

(d) *Fungus*. Any of a large division of plants, including dermatophytes, yeasts, and molds, characterized by a simple cell structure and the absence of chlorophyll.

(e) *Jock itch*. A chronic and recurrent infection caused by certain dermatophytic fungi; affects the upper, inner thighs and sometimes extends to the groin and the pubic area; the condition most frequently occurs in men, but may also occur in women.

(f) *Ringworm*. A skin infection caused by certain dermatophytic fungi.

### § 333.210 Antifungal active ingredients.

The active ingredient of the product consists of any one of the following within the specified concentration established for each ingredient:

- (a) Clotrimazole 3 percent.
- (b) Haloprogin 1 percent.
- (c) Miconazole nitrate 2 percent.
- (d) Povidone-iodine 10 percent.
- (e) Tolnaftate 1 percent.

(f) Undecylenic acid, calcium undecylenate, copper undecylenate, and zinc undecylenate may be used individually or in any ratio that provides a total undecylenate concentration of 10 to 25 percent.

### § 333.250 Labeling of antifungal drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antifungal."

(b) *Indications*. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1)(i) of this section and may contain the additional phrase listed in

paragraph (b)(1)(ii) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) *For products containing any ingredient identified in § 333.210 labeled for the treatment of athlete's foot, jock itch, and ringworm*. (i) (Select one of the following: "Treats," "For the treatment of," "For effective treatment of," "Cures," "For the cure of," "Clears up," or "Proven clinically effective in the treatment of") (select one condition from any one or more of the following groups of conditions:

(A) "Athlete's foot," athlete's foot (dermatophytosis)," "athlete's foot (tinea pedis)," or "tinea pedis (athlete's foot)";

(B) "Jock itch," "jock itch (tinea cruris)," or "tinea cruris (jock itch)"; or

(C) "Ringworm," "ringworm (tinea corporis)," or "tinea corporis (ringworm).")

(ii) In addition to the information identified in paragraph (b)(1)(i) of this section, the labeling of the product may contain the following statement: (Select one of the following: "Relieves," "For relief of," "For effective relief of," or "Soothes,") (select one or more of the following: "Itching," "scaling," "cracking," "burning," "redness," "soreness," "irritation," "discomfort," "chafing associated with jock itch," "itchy, scaly skin between the toes," or "itching, burning feet").

(2) *For products containing the ingredient identified in § 333.210(e) labeled for the prevention of athlete's foot*. (i) (Select one of the following: "Clinically proven to prevent," "Prevents," "Proven effective in the prevention of," "Helps prevent", "For the prevention of," "For the prophylaxis (prevention) of,"

“Guards against,” or “Prevents the recurrence of”) (select one of the following: “Athlete’s foot,” “athlete’s foot (dermatophytosis),” “athlete’s foot (tinea pedis),” or “tinea pedis (athlete’s foot)”) “with daily use.”

(ii) In addition to the information identified in paragraph (b)(2)(i) of this section, the labeling of the product may contain the following statement: “Clears up athlete’s foot infection and with daily use helps keep it from coming back.”

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) *For products containing any ingredient identified in § 330.210.* (i) “Do not use on children under 2 years of age unless directed by a doctor.”

(ii) “For external use only.”

(iii) “Avoid contact with the eyes.”

(2) *For products labeled according to paragraph (b)(1) of this section for the treatment of athlete’s foot and ringworm.* “If irritation occurs or if there is no improvement within 4 weeks, discontinue use and consult a doctor.”

(3) *For products labeled according to paragraph (b)(1) of this section for the treatment of jock itch.* “If irritation occurs or if there is no improvement within 2 weeks, discontinue use and consult a doctor.”

(4) *For products labeled according to paragraph (b)(2) of this section for the prevention of athlete’s foot.* “If irritation occurs, discontinue use and consult a doctor.”

(5) *For products containing the ingredient identified in § 333.210(a) labeled according to paragraph (b)(1) of this section.* The following statements must appear in boldface type as the first warnings under the “Warnings” heading. (i) “Do not use on children under 2 years of age.” (This warning is to be used in place of the warning in paragraph (c)(1)(i) of this section.)

(ii) “Do not use for diaper rash.”

(d) *Directions.* The labeling of the product contains the following statements under the heading “Directions”:

(1) *For products labeled according to paragraph (b)(1) of this section for the treatment of athlete’s foot, jock itch, and ringworm.* [Select one of the following: “Clean” or “Wash”] “the affected area

and dry thoroughly. Apply” (the word “spray” may be used to replace the word “apply” for aerosol products) “a thin layer of the product over affected area twice daily (morning and night) or as directed by a doctor. Supervise children in the use of this product. For athlete’s foot: Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily. For athlete’s foot and ringworm, use daily for 4 weeks; for jock itch, use daily for 2 weeks. If condition persists longer, consult a doctor. This product is not effective on the scalp or nails.”

(2) *For products labeled according to paragraph (b)(2) of this section for the prevention of athlete’s foot.* “To prevent athlete’s foot,” (select one of the following: “clean” or “wash”) “the feet and dry thoroughly. Apply” (the word “spray” may be used to replace the word “apply” for aerosol products) “a thin layer of the product to the feet once or twice daily (morning and/or night). Supervise children in the use of this product. Pay special attention to spaces between the toes; wear well-fitting, ventilated shoes, and change shoes and socks at least once daily.”

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

#### § 333.280 Professional labeling.

The labeling provided to health professionals (but not to the general public) may contain the following additional indication:

(a) *For products containing haloprogin or miconazole nitrate identified in § 333.210 (a) and (c).* “For the treatment of superficial skin infections caused by yeast (*Candida albicans*).”

(b) [Reserved]

#### Subpart D—Topical Acne Drug Products

SOURCE: 56 FR 41019, Aug. 16, 1991, unless otherwise noted.

#### § 333.301 Scope.

(a) An over-the-counter acne drug product in a form suitable for topical application is generally recognized as

safe and effective and is not misbranded if it meets each of the conditions in this subpart and each general condition established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

### § 333.303 Definitions.

As used in this subpart:

(a) *Acne*. A disease involving the oil glands and hair follicles of the skin which is manifested by blackheads, whiteheads, acne pimples, and acne blemishes.

(b) *Acne blemish*. A flaw in the skin resulting from acne.

(c) *Acne drug product*. A drug product used to reduce the number of acne blemishes, acne pimples, blackheads, and whiteheads.

(d) *Acne pimple*. A small, prominent, inflamed elevation of the skin resulting from acne.

(e) *Blackhead*. A condition of the skin that occurs in acne and is characterized by a black tip.

(f) *Whitehead*. A condition of the skin that occurs in acne and is characterized by a small, firm, whitish elevation of the skin.

### § 333.310 Acne active ingredients.

The active ingredient of the product consists of any of the following when labeled according to § 333.350.

(a) Resorcinol 2 percent when combined in accordance with § 333.320(a).

(b) Resorcinol monoacetate 3 percent when combined in accordance with § 333.320(b).

(c) Salicylic acid 0.5 to 2 percent.

(d) Sulfur 3 to 10 percent.

(e) Sulfur 3 to 8 percent when combined in accordance with § 333.320.

### § 333.320 Permitted combinations of active ingredients.

(a) Resorcinol identified in § 333.310(a) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

(b) Resorcinol monoacetate identified in § 333.310(b) when combined with sulfur identified in § 333.310(e) provided the product is labeled according to § 333.350.

### § 333.350 Labeling of acne drug products.

(a) *Statement of identity*. The labeling of the product contains the established name of the drug, if any, and identifies the product as an "acne medication," "acne treatment," "acne medication" (insert dosage form, *e.g.*, "cream," "gel," "lotion," or "ointment"), or "acne treatment" (insert dosage form, *e.g.*, "cream," "gel," "lotion," or "ointment").

(b) *Indications*. The labeling of the product states, under the heading "Indications," the phrase listed in paragraph (b)(1) of this section and may contain any of the additional phrases listed in paragraph (b)(2) of this section. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) "For the" (select one of the following: "management" or "treatment") "of acne."

(2) In addition to the information identified in paragraph (b)(1) of this section, the labeling of the product may contain any one or more of the following statements:

(i) (Select one of the following: "Clears," "Clears up," "Clears up most," "Dries," "Dries up," "Dries and clears," "Helps clear," "Helps clear up," "Reduces the number of," or "Reduces the severity of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads") which may be followed by "and allows skin to heal."

(ii) "Penetrates pores to" (select one of the following: "eliminate most," "control," "clear most," or "reduce the number of") (select one or more of the following: "acne blemishes," "acne pimples," "blackheads," or "whiteheads").

(iii) "Helps keep skin clear of new" (select one or more of the following:



“acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”).

(iv) “Helps prevent new” (select one or more of the following: “acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”) which may be followed by “from forming.”

(v) “Helps prevent the development of new” (select one or more of the following: “acne blemishes,” “acne pimples,” “blackheads,” or “whiteheads”).

(c) *Warnings.* The labeling of the product contains the following warnings under the heading “Warnings”:

(1) *For products containing any ingredient identified in § 333.310.* (i) “For external use only.”

(ii) “Using other topical acne medications at the same time or immediately following use of this product may increase dryness or irritation of the skin. If this occurs, only one medication should be used unless directed by a doctor.”

(2) *For products containing sulfur identified in §§ 333.310 (d) and (e).* “Do not get into eyes. If excessive skin irritation develops or increases, discontinue use and consult a doctor.”

(3) *For products containing any combination identified in § 333.320.* “Apply to affected areas only. Do not use on broken skin or apply to large areas of the body.”

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”:

(1) “Cleanse the skin thoroughly before applying medication. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. If bothersome dryness or peeling occurs, reduce application to once a day or every other day.”

(2) The directions described in paragraph (d)(1) of this section are intended for products that are applied and left on the skin. Other products, such as soaps or masks, may be applied and removed and should have appropriate directions.

(3) *Optional directions.* In addition to the required directions in paragraphs

(d)(1) and (d)(2) of this section, the product may contain the following optional labeling: “*Sensitivity Test for a New User.* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated: (select one of the following: ‘elsewhere on this label,’ ‘above,’ or ‘below.’)”

(e) The word “physician” may be substituted for the word “doctor” in any of the labeling statements in this section.

## PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

### Subpart A—General Provisions

Sec.

336.1 Scope.

336.3 Definition.

### Subpart B—Active Ingredients

336.10 Antiemetic active ingredients.

### Subpart C—Labeling

336.50 Labeling of antiemetic drug products.

336.80 Professional labeling.

AUTHORITY: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

SOURCE: 52 FR 15892, Apr. 30, 1987, unless otherwise noted.

### Subpart A—General Provisions

#### § 336.1 Scope.

(a) An over-the-counter antiemetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

#### § 336.3 Definition.

As used in this part:

*Antiemetic.* An agent that prevents or treats nausea and vomiting.